

# Axela, Inc.- Zplex Automated Work Station



## GENERAL DESCRIPTION:

The Zplex® is a automated microarray platform that is designed for routine and focused multiplex analysis for both RNA and protein research. The Zplex uses a highly reproducible, medium density array to provide users with expression information. It uniquely combines and automates three separate functions (biomolecular binding, washing/labeling and imaging) into a single bench top instrument. Other features of the Zplex® include:



- Flow-Thru Microarray Chip Technology that enables fast oligonucleotide hybridization and protein binding
- Medium Density Microarrays that provides quantitative data on 120 or more different biomarkers
- Automated functionality minimizing user interaction to only sample preparation, workflow entry, and sample/reagent loading
- Rapid Throughput running up to 8 gene expression samples per run in just 3 hours allowing up to 24 tests per day
- Built-in image capture and analysis software
- High Sensitivity for low abundant biomarkers
- Single, Robust Platform for both gene and protein expression analysis
- Affordable with low cost per data point.

## TECHNICAL DESCRIPTION:

Axela's automated Zplex System uses a unique flow thru technology within a single-use TipChip consumable. The TipChip is a disposable device consisting of a 6.5 mm square chip mounted on a plastic tube. The chip is made of porous silicon with >200,000 microchannels. This approach facilitates the interaction between target molecules and immobilized probes resulting in fast oligonucleotide hybridization or protein binding. Features of the TipChip Arrays are the following:

- Ideal for automated multiplex analysis of gene and protein expression
- Designed to contain up to 576 spots per chip ("features")
- Each microarray can provide quantitative data on 120 or more different biomarkers.
- Up to eight TipChip arrays can be run on the Zplex system simultaneously
- Binding activity on each feature is detected by chemiluminescence using a CCD camera

The embedded software built into the Zplex System automatically analyzes the images, quality controls the data and outputs the microarray data.

## Tier Selection

Final tier assignment is based on overall product score.

- Top Tier
- Second Tier
- Third Tier
- ◐ Fourth Tier
- Bottom Tier

### RANKINGS

	Biological	Chemical	Radiological
<b>FIELD USE System</b>	● Bottom Tier	○ N/A	○ N/A
<b>MOBILE Laboratory</b>	○ Third Tier	○ N/A	○ N/A
<b>DIAGNOSTIC Laboratory</b>	● Second Tier	○ N/A	○ N/A
<b>ANALYTICAL Laboratory</b>	● Second Tier	○ N/A	○ N/A

## Survey Source

Vendor Supplied Information

## CONTACT INFORMATION

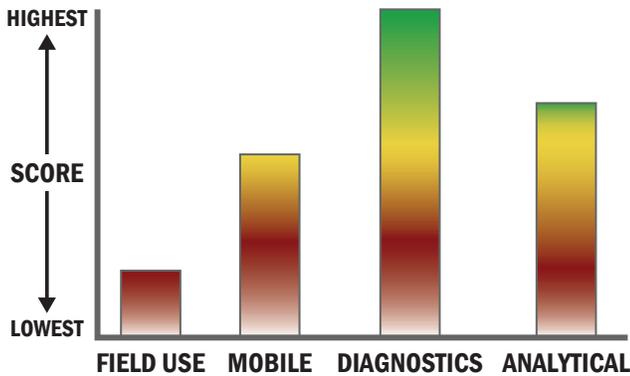
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## COST

- \$85,000/system
- \$75-\$100/analysis

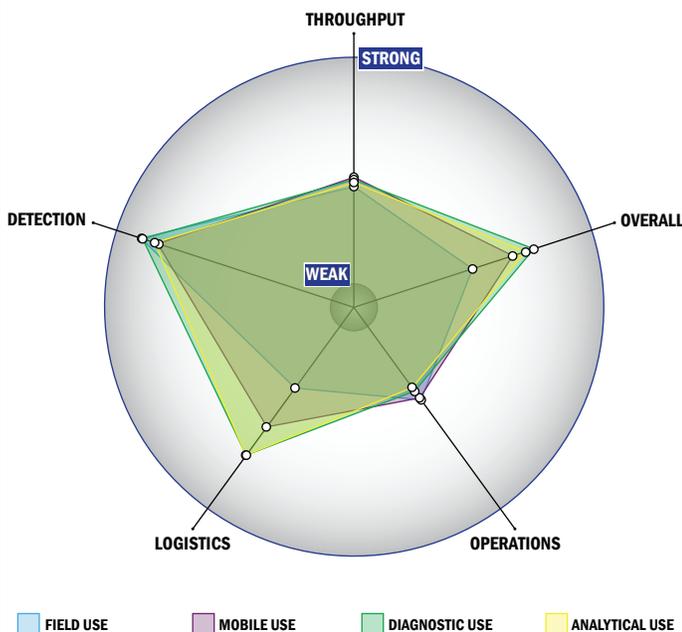
## Scoring Analysis

System scores are compared across the four scenarios and ranked from highest to lowest.



## Impact Chart

The Impact Chart is a spider graph representing specific categories and designed to give the reader a visual depiction of how a particular system is expected to operate across the four different scenarios. The score for each of the seven categories is presented as the percentage of the total possible score. Higher category scores extend the spokes of a graphic toward the outer edge of the chart. The area graphed for each of the four scenarios relates to how well the system performed in that scenario. Graphics for each of the four scenarios are super-imposed for ease of comparison.



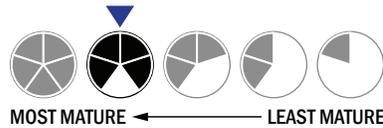
## Evaluation Criteria

### Throughput:

- Between 60 minutes and 8 hours for detection
- Multiple samples, multiple tests/sample per run
- Less than 32 samples every 2 hours
- The system or device is currently fully automated
- Device or system is intended for multiple detection assays
- 5 or more solutions, buffer, eluents, and/or reagents
- 2 components
- Less than 5 minutes is required for set-up
- 6-8 steps are required for detection

### Logistics:

- An afternoon of training and some technical skills required
- Approximately the size of a home dishwasher
- More than 50 kg
- Wired connections are available
- System or device has 110V electrical requirement



### Operations:

- Can be used from 4 °C to 37 °C
- Components must be frozen (-20 °C)
- Device or system has peak performance at normal relative humidity conditions
- Between 1 to 3 years shelf life
- 5-10 years expected life
- Results cannot be viewed in real-time
- The system is not capable of autonomy
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

### Detection:

- Possible the system could receive 510K clearance, no current efforts at this time
- Efforts are underway to achieve FDA approval
- Less than 50 µL
- Excellent specificity. System has occasional false alarms under certain conditions (<2%)
- 1-100 CFU per mL
- 1-100 PFU per mL
- Less than 1 ng per mL
- Manual kit not integrated with the system handles spore lysis.